REMARKS

Claim 1 and 3 have been amended. Support for the amendments may be found throughout the specification and particularly in Figure 5. No other claims have been amended, added, or deleted, and no new matter has been added. Claims 1, 3-6, 8, and 9 remain pending.

Claim Rejections – 35 USC § 103(a)

Claims 1 and 3 stand rejected under 35 USC § 103(a) as allegedly being unpatentable as obvious over US 5,013,296 ("Buckberg") in view of US 6,267,747 ("Samson"). These rejections are traversed.

Independent claims 1 and 3 have been amended to recite that the inserted membrane is opened "upon emergence from a distal end of the lumen" and the opened membrane is advanced "away from the distal end of the lumen until it covers the aortic valve at a deployment position below the coronary arteries" thereby preventing the cardioplegia solution from entering the left ventricle through the aortic valve and trapping the cardioplegia solution above the membrane and below the cross-clamp so as to force the cardioplegia solution down the coronary arteries. Thus, the membrane is opened and moved into place downstream from the cardioplegia delivery position so as to prevent the cardioplegia solution from passing through an incompetent aortic valve into the left ventricle while simultaneously forcing the cardioplegia solution down the coronary arteries as desired. No inflation of the membrane is necessary. Moreover, since the membrane is advanced away from the distal end of the lumen, the distal end of the lumen may be used for cardioplegia delivery, rather than requiring the cardioplegia solution to seep out of a porous portion of the lumen side walls aligned with the coronary ostia as in Samson. Such features are not shown or suggested by the cited references.

As noted in previous replies, Buckberg discloses a conventional cardioplegia cannula that is inserted into the aortic root beneath a clamp for administration of cardioplegia solution. Such a device is quite similar to that illustrated in prior art Figure 2 of the present application. The examiner again acknowledged on page of the Official Action that Buckberg does not disclose "a folded non-porous membrane to cover the aortic valve nor the use of such a membrane." Applicant further notes that Buckberg does not recognize or address the problem of leakage of

cardioplegia solution into the left ventricle through the aortic valve during administration of the cardioplegia solution.

To address such shortcomings in the teachings of Buckberg, the examiner again cites Samson's teachings of an aortic catheter that uses a balloon to occlude blood flow in the aortic root and concludes that one skilled in the art would have modified the cannula of Buckberg to deliver a balloon as taught by Samson to block the aortic root and aortic valve to prevent the aortic root from experiencing significant retrograde fluid pressure. Applicant respectfully disagrees with the examiner's conclusions and again traverses the rejections over the teachings of Buckberg and Samson.

As is clear from Figure 5 of the present application and the related discussion in paragraph [0024] of the specification, the claimed methods and cannula address the problem of leakage through the aortic valve during cardioplegia delivery. Neither Buckberg nor Samson addresses this issue.

Samson instead teaches that by delivering cardioplegia solution directly to the coronary arteries that Samson's aortic root balloon perfusion catheter purportedly does not cause significant retrograde fluid pressure that would cause cardioplegia solution to be forced through the aortic valve into the left ventricle. Applicant notes further that Samson does not account for an incompetent or open aortic valve that would leak even if "significant retrograde fluid pressure" were not created. Samson thus does not address the problem addressed by the claimed method and cannula.

Moreover, the geometry of the cannula disclosed by Samson would preclude the possibility of inserting a membrane through Samson's or Buckberg's catheter that would trap the cardioplegia solution "above the membrane and below the cross-clamp so as to force the cardioplegia solution down the coronary arteries" as claimed. As previously noted, Samson uses a distal flow control member in the form of a porous aortic root member that is configured to deliver the cardioplegia solution to the coronary ostia while occluding the ascending aorta. When in place, the cannula of Samson occludes the ascending aorta with the expanded balloon of the aortic root balloon perfusion catheter but does not provide anything to occlude the leakage of cardioplegia fluid through the aortic valve into the left ventricle. Also, as noted at column 6,

lines 41-55, the porous root balloon is mounted distally and delivers the cardioplegia solution through a porous material 126 of the porous root balloon to provide a controlled volume of fluid that may perfuse the coronary arteries. Since Samson is concerned with controlling the flow of cardioplegia fluid to the aortic valve to avoid significant retrograde fluid pressure, it is clear that Samson did not teach or contemplate using a membrane to trap the cardioplegia solution above the membrane and below the cross-clamp so as to force the cardioplegia solution down the coronary arteries as claimed. In other words, Samson relies upon low pressure perfusion that "does not challenge the competence of the aortic valve" instead of blocking the aortic valve with a membrane as claimed.

In rebuttal to this, the examiner now further alleges in the Official Action that Samson teaches placing the balloon just above the aortic valve so as to "prevent[s] the cardioplegia solution from entering the left ventricle through the aortic valve" and trapping the cardioplegia solution above the membrane and below the cross-clamp "so as to force the cardioplegia solution down the coronary arteries" as claimed. However, the cannula of Samson does not work in this manner. Rather, as noted, for example, at column 9, line 63, to column 10, line 10, of Samson, the distal flow control member (416) prevents seepage of cardioplegia fluid through the porous portion (432) by contacting the aortic wall with portions of the porous windows not aligned with the coronary ostia. This cardioplegia solution thus seeps out of the catheter and contacts the aortic valve, although without significant pressure so as to "challenge the competence of the aortic valve." Applicant submits that this design permits cardioplegia solution to flow through an incompetent aortic valve to the coronary arteries – even when the balloon is placed just above the aortic valve.

The claimed invention addresses this shortcoming in Samson by advancing a foldable membrane away from the distal end of the lumen so that the membrane may cover the aortic valve to prevent the cardioplegia solution from entering (or seeping into) the coronary arteries through the aortic valve. Also, since the membrane is moved away from the distal end of the lumen, the cardioplegia solution may be delivered with more pressure out the end of the lumen (i.e., no relying upon seepage) to provide a more robust and efficient delivery of the cardioplegia solution. Such an approach is not taught by Samson.

Accordingly, even if one skilled in the art would have known to combine the teachings of Buckberg and Samson as the examiner alleges, the claimed method and cardioplegia cannula would not have resulted for at least two reasons. First, since Samson uses low pressure perfusion that "does not challenge the competence of the aortic valve," Samson would not motivate one skilled in the art to block the aortic valve as claimed to prevent fluid flow into the left ventricle absent a recognition that an incompetent aortic valve would allow leakage into the left ventricle. Samson provides no such teachings. Second, neither Buckberg nor Samson teaches advancing the membrane through a lumen and away from the distal end of the lumen to deliver the opened membrane to the aortic valve as claimed. Withdrawal of the rejection of claims 1 and 3 as being unpatentable as obvious over Buckberg and Samson is thus appropriate and is solicited.

Claims 4-6, 8, and 9 stand rejected under 35 USC § 103(a) as allegedly being unpatentable as obvious over Buckberg and Samson further in view of US 6,638,293 ("Makower"). These rejections are also traversed.

As claims 4-6 depend from claim 3, and claims 8 and 9 depend from claim 1, these claims are patentable over Buckberg and Samson for at least the reasons set forth above with respect to claims 1 and 3. Moreover, Applicant submits that Makower does not provide any teachings that address the aforementioned deficiencies in the teachings of Buckberg and Samson. The examiner alleges that Makower teaches an umbrella membrane that is opened either using a wire or that springs open where both the wire and umbrella are made of nitinol and that such teachings would have been combined with the teachings of Buckberg and Samson by one skilled in the art to arrive at the claimed methods and cardioplegia cannula. Applicant respectfully disagrees.

Makower discloses a variety of lumen blocking apparatuses that may be delivered transluminally through the patient's vasculature. However, like Buckberg and Samson, Makower does not recognize the problem of aortic valve leakage or provide any solution to such leakage during administration of cardioplegia solution. Also, Makower does not teach a method or cardioplegia cannula configuration whereby the cardioplegia solution is trapped above the deployed membrane and below the cross-clamp so as to force the cardioplegia solution down the coronary arteries as claimed. Accordingly, even if one skilled in the art would have used the

teachings of Makower to advance the membrane through a lumen and deliver the opened membrane to the distal end of the lumen, the teachings of Makower would have taught one skilled in the art to do this to stop blood flow, not to block the aortic valve downstream from the end of the lumen as claimed to prevent fluid flow into the left ventricle. In other words, Makower does not overcome Samson's contrary teachings of using low pressure perfusion that "does not challenge the competence of the aortic valve" instead of advancing a membrane through and out the end of the lumen to cover the aortic valve as claimed. Since Makower does not overcome the deficiencies in the teachings of Buckberg and Samson, withdrawal of the rejection of claims 4-6, 8, and 9 is thus appropriate and is solicited.

For at least the reasons set forth herein, claims 1, 3-6, and 8-9 are believed to be allowable over Buckberg, Samson, and Makower. None of the cited art suggests occluding the aortic valve to prevent the leakage of cardioplegia solution into the left ventricle via the aortic valve as claimed. Withdrawal of all rejections is solicited.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims, as amended, are in a condition for allowance. Applicants respectfully request the issuance of a Notice of Allowability.

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